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Title

Shared Medical Appointments: An Academic-Community Partnership to Improve Care Among Adults With Type 2 Diabetes in California Central Valley Region.

Permalink

<https://escholarship.org/uc/item/3cw6v913>

Journal

The Diabetes educator, 46(2)

ISSN

0145-7217

Authors

Noya, Carolina
Alkon, Abbey
Castillo, Elizabeth
et al.

Publication Date

2020-04-01

DOI

10.1177/0145721720906792

Peer reviewed

Shared Medical Appointments

An Academic-Community Partnership to Improve Care Among Adults With Type 2 Diabetes in California Central Valley Region

Purpose

The purpose of the study was to evaluate the effectiveness of ALDEA (Latinos con Diabetes en Acción), a Shared Medical Appointment (SMA) intervention, compared to usual primary care (UPC) for the treatment of adults with type 2 diabetes over a 6-month period. It was hypothesized that participants in the SMA will have greater reductions in A1C at 6 months post-intervention compared to the control group.

Methods

This study was a quasi-experimental design with a non-randomized matched control group that followed participants prospectively for 6 months. All adults living with type-2 diabetes receiving primary care at a 2 FQHC clinics were eligible for inclusion. Participants in the control group were matched retrospectively on baseline A1C and age.

Results

The reductions in A1C were greater in the ALDEA SMA intervention group relative to the UPC control group at 6 months in both of the FQHC centers and in the combined sample.

Conclusions

This study demonstrated that patients in the ALDEA program had a significantly greater reduction in A1C at

Carolina Noya, PhD, RN, FNP-C 

Abbey Alkon, PhD, RN, FAAN

Elizabeth Castillo, MS, RN, FNP-C

Angel Chen Kuo, MSN, RN, CPNP-BC

Elizabeth Gatewood, DNP, RN, FNP-C, CNE 

From University of California San Francisco, School of Nursing, San Francisco, California (Dr Noya, Dr Gatewood, Dr Alkon, Ms Castillo, Ms Kuo).

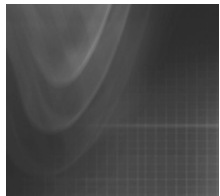
Correspondence to Carolina Noya, UCSF School of Nursing, 2 Koret Way, N411N, San Francisco, CA 94143-0606, USA (carolina.noya@ucsf.edu).

Financial Acknowledgment: This project was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant No. D09HP28680, Advanced Nursing Education. This information or content and conclusions are those of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS, or the US government.

Additional Acknowledgment: The authors gratefully acknowledge the commitment and support of the collaborating organizations, including Yolanda Solis, Patricia Jimenez, Stayci Sepeda, Dawn Wells, and Raquel Ramos Garcia from Altura Centers for Health; Virginia Rivera from Community Medical Centers; and Nathaniel Lara, Yasmin Policarpe, and Cristina Vargas from Camarena Health.

DOI: 10.1177/0145721720906792

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6 months compared to the control group. Despite its limitations, the ALDEA SMA program was successful in empowering patients and improving glycemic control.

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Diabetes has reached epidemic proportions in the United States. In 2017, the Centers for Disease Control and Prevention reported that approximately 30.3 million people have diabetes, representing 9.4% of the US population.¹ Disparities in the prevalence rates of type 2 diabetes and quality of diabetes care are found at the intersection of class, race, and ethnicity. People who are uninsured and people of lower socioeconomic status suffer disproportionately high morbidity and disability from diabetes.² For people with diabetes confronting structural barriers to health, such as lack of health insurance and/or transportation, poverty, racism, and food insecurity, diabetes self-management education is often not attainable.^{3,4} Federally Qualified Health Centers (FQHCs) are at the forefront of providing care to medically underserved communities.⁵

Despite a steady and slow improvement over the past 10 years in achieving recommended goals for glycated hemoglobin (A1C), blood pressure (BP), and low density lipoprotein (LDL), about half of the adults with diabetes continue to miss target goals (33%-49%).⁶ Nationally, only 19% of adults with diabetes meet all 3 target goals (A1C, BP, and LDL) and are nonsmokers.⁶ Furthermore, only half of adults with diabetes have had formal diabetes self-management education and support (DSMES) despite the American Diabetes Association (ADA) recommendation and the mounting evidence supporting DSMES as a critical component of diabetes care.^{6,7}

Shared medical appointments (SMAs) have become an increasingly popular model to improve the quality of diabetes care and access to education.⁸⁻¹² SMAs are a promising alternative to individual office visits because DSMES and peer support are integrated within the SMA visit, collaborative relationships between providers and patients can be nurtured, and group activities can be used to refine patients' disease management skills and enhance knowledge.¹³

Research on the effectiveness of SMAs to improve diabetes outcomes for adults with type 2 diabetes has emerged, and there is sufficient evidence on the positive impact of SMAs on important outcomes, A1C and BP. Unfortunately, the current literature on SMA effectiveness

has, for the most part, excluded monolingual Spanish-speaking Latinos (MSL) and other racial and ethnic minorities despite these populations' disproportionate burden of the disease.¹⁴ A recent study by Noya and colleagues¹⁵ demonstrated that a culturally adapted SMA model among monolingual Latinxs was effective in reducing A1C at 6 months an additional 0.83% compared to the control group ($b = -0.83$, $t = -2.25$, $P = .03$). Therefore, there is support for the implementation of SMAs among adults with type 2 diabetes.^{8,13,15} Two separate meta-analyses revealed that SMAs improved A1C by 0.6% to 0.7%.^{8,13} Although a change of 0.6% to 0.7% may seem modest, based on the United Kingdom Prospective Diabetes Study (UKPDS) findings,¹⁶ a decrease of 0.6% A1C translates to a decrease of approximately 10.5% of the overall deaths related to diabetes, 7% of the myocardial infarctions, and 19% of microvascular complications.

Although the literature demonstrates that SMAs improve outcomes in patients with type 2 diabetes, there are also a number of identified barriers to participation in educational programs. In a recent metanalysis, these were identified as either those who could not attend (logistical, medical, or financial barriers) or those who choose not to attend (no perceived benefit, cultural barrier, knowledge).¹⁷ One study specifically examining Latinx patients' participation in SMA noted lack of culturally relevant marketing and scheduling barriers as likely barriers to participation.¹⁸

The present study was part of an academic-community partnership aimed to improve the care of adults with type 2 diabetes living in 2 different rural counties in Northern California. Informed written consent was obtained in English or Spanish. The Institutional Review Board at the University of California, San Francisco approved the study, including the protocol and consent forms (IRB No. 16-21252).

The purpose of this study is to evaluate the effectiveness of the ALDEA SMA Program (Latinos con Diabetes en Acción) at 2 rural FQHCs with a multiethnic group of adults with type 2 diabetes, compared to usual primary care (UPC) over a 6-month period.

Study Design

Design

This study was a quasi-experimental design with a nonrandomized matched UPC control group that followed patients prospectively for 6 months.

Table 1

Cultural Adaptation of ALDEA Shared Medical Appointment Model

Issues to Consider		Adaptation
Philosophy		<ul style="list-style-type: none"> • Empowerment model • Patient driven; patient as experts
Patient education		<ul style="list-style-type: none"> • Patient-driven curriculum • Adapted for low health literacy • Behavioral approaches (motivational interviewing, SMART goals, problem solving)
Social determinants	Low SES/insurance status	<ul style="list-style-type: none"> • Low-cost pharmacy • Low-cost/free diabetes supplies
Cultural considerations	LHL	<ul style="list-style-type: none"> • Screening for LHL included in intake form
	Food insecurity	<ul style="list-style-type: none"> • Food distribution established on site
	Language barriers	<ul style="list-style-type: none"> • Bicultural and bilingual team
	<i>Respeto</i>	<ul style="list-style-type: none"> • Cultural humility training for bicultural and bilingual team
	<i>Familismo</i>	<ul style="list-style-type: none"> • Family members invited to participate • Consideration of family in planning and execution of SMART goals
	Time orientation	<ul style="list-style-type: none"> • Flexible schedule, late arrival normalized
	Herbal medicine	<ul style="list-style-type: none"> • Use of herbal medicine integrated into intake form
Abbreviations: LHL, low health literacy; SES, socioeconomic status.		

Hypothesis

It was hypothesized that participants in the ALDEA SMA would have greater reductions in A1C at 3- and 6-months postintervention compared to the UPC control group.

Methodology

The methodology will be described in 2 sections: first, the methodology that is shared by both sites followed by each site's unique characteristics.

Sample Selection

Inclusion criteria required patients >18 years of age with type 2 diabetes and attendance of at least 3 SMA sessions over the course of the program. Patients were referred by their primary care providers, medical assistants, and/or health educators. They were recruited via flyers and phone calls using the diabetes registry at the FQHCs. The UPC control group was a retrospective, nonrandom, matched sample who met the aforementioned inclusion criteria and received UPC at the FQHC site. The UPC control group was selected via medical

record review. Each intervention participant was matched by age (within 5 years) and A1C levels (within 0.5%-1%) with a UPC control group participant. Each SMA participant was matched with their controls within the same timeframe of the intervention so that baseline and follow-up data were consistent over time.

All patients with an A1C >9% were offered participation in the intervention. Due to the extensive outreach including flyers, we are unable to know how many eligible patients were aware of the SMA program. Written consent in both English and Spanish was available. Patients provided consent in their language of preference prior to the start of the study. Based on previous literature, we hypothesized that the intervention group's average change in A1C from baseline to 6 months would be 1.48% (SD = 2.22).¹⁵ It was hypothesized that the control group would have no change in A1C. The difference between a 1.48 (2.22) mean (SD) change and no change can be expressed as an effect size of .667. Using the nQuery Advisor power program for a *t* test with unequal sample sizes between 2 independent groups, with a 1:2 ratio, 80% power to detect the effect size of .667, and a 2-tailed alpha of .05, the total sample size would need to be 84 (eg, 28 intervention and 56 control group participants).

Intervention: ALDEA SMA

ALDEA is a culturally tailored SMA program. The structure of the SMA intervention was based on the model refined by the Veterans Affairs Office.¹¹ In this model, groups include peer support, DSMES with a focus on behavioral approaches (SMART goals and problem solving), and medical management. SMART goals are specific, measurable, agreed on, realistic, and time-based. The ALDEA model is unique in that it does not have a set curriculum, maintains open enrollment, and has a flexible late policy. Topics are decided on by participants rather than by the provider or health educator. Open enrollment allows participants to join the group at any point of time. Additionally, participants have flexibility in attendance and are permitted to join even if late or having missed group sessions. Each of the FQHC partners adhered to the main characteristics of the ALDEA program, with a bilingual and bicultural health care team to support an open enrollment program that was based off of an empowerment model with a patient-driven, culturally specific curriculum while utilizing behavioral approaches with patients and families (motivational interviewing, setting SMART goals, and using problem solving strategies). Table 1 provides a description of adaptive changes made to the model.

Clinical partners had autonomy in deciding the frequency of their SMA program and the composition of the health care team. The health care team differed in that Site 1 had a nurse practitioner as the lead clinician, and Site 2 had a physician as the lead clinician. Both FQHC SMA teams included a medical assistant, a health educator, and a front office administrator. Additionally, the periodicity and intensity of the SMA interventions varied between sites, with Site 1 offering weekly sessions and Site 2 offering SMA bimonthly. At Site 2, an education group was offered during the alternate weeks.

Control: Usual Primary Care

The UPC patients received the standard of care for patients with diabetes consisting of quarterly individual medical visits with a primary care provider (ie, MD, family nurse practitioner [FNP], or physician's assistant [PA]) of approximately 20 minutes. Referrals to DSMES in the community were made routinely as part of standard of care.

Setting

Two FQHC clinics were identified from within a consortium of 13 FQHC networks that serve as primary care

medical homes to a diverse population of medically underserved individuals and families located in the Central Valley (CV) of California. The CV is the fastest growing region in California and one of the most productive agricultural regions in the world. The CV is comprised of 19 counties, ranging from isolated rural agricultural areas to rapidly expanding urban centers. This FQHC consortium serves more than 600 000 patients annually in more than 145 community health centers; migrant and seasonal farmworkers make up over 40% of patients served. An area of high health care needs, all CV counties include federally designated health professional shortage areas.¹⁹ Clients from within these FQHCs experience high rates of chronic health conditions, such as diabetes, obesity, and asthma, and are at high risk for poor pregnancy and birth outcomes, including preterm birth.²⁰

Site 1 is at an FQHC located in the northeast sector of the CV, a generally rural, agricultural district with a large migrant worker population. They serve 87 000 patients annually, 90% of whom earn below 200% of the federal poverty level; 87% are non-English speakers; and 12% are migrant or seasonal farmworkers. At this location, 2 separate groups were formed, 1 for Spanish-speaking Latinxs and 1 for all English speakers.

Site 2 is at an FQHC located in the heart of the CV providing care to 26 735 patients annually. The patient population is predominantly Latinx (74%), 31% is best served in another language (primarily Spanish), 96% earns below 200% of the federal poverty level, 73% is insured by Medi-Cal, and 21% are migrant or seasonal workers. At this site, a single group for Spanish-speaking Latinxs was implemented.

Measures

Demographic variables were obtained from the medical records retrospectively for the intervention and UPC control group patients, as were laboratory values of A1C, systolic and diastolic BP, and LDL at baseline, 3 months and 6 months after baseline.

Demographic Variables

The following demographic data were collected at baseline: chronological age (in years), sex, ethnicity (patients' self-identification), poverty level (per federal guidelines), and health insurance (yes or no for any type of comprehensive insurance, public or private payer).

Outcome/Metabolic Variables

A1C was measured with a high-performance liquid chromatography method used by the Bio-Rad Hercules laboratory. Data were obtained at baseline and 3 and 6 months. If a participant had more than 1 measurement in a 90-day interval, the average of all A1C levels collected during the interval was used. A1C levels obtained within 24 hours of the first SMA appointment were considered to be pre-SMA baseline data. Post-SMA data points were calculated as time from first SMA appointment. Data from all patients were then aggregated based on corresponding time intervals every 3 months. Quarterly measures of A1C are part of the ADA guidelines of care for people with diabetes and were routinely collected in this clinic.

The value of the last LDL closest to the 6-month postintervention data collection point was utilized. Per current ADA guidelines, the LDL variable was dichotomized (yes/no) as to whether the participant achieved the recommendation of LDL <100 mg/dL.²¹

Blood pressure, both systolic (SBP) and diastolic (DBP), were measured using calibrated manual cuffs, taken by a medical assistant or nurse practitioner student at each clinic or SMA visit. Blood pressure values closest to the 6-month time postbaseline data collection point were used for analysis. Per current guidelines, the BP variable was dichotomized (yes/no) as to whether the participant achieved the ADA recommendation of <140/90 mmHg.²¹

Data Analysis

Data entry and statistical analyses were conducted using SPSS 19. Descriptive statistics were used to summarize the data and identify outliers. Differences in the demographics and study variables between the SMA intervention group and the UPC control group were calculated using Student's *t* test for independent groups, chi-square, or Fisher exact tests.

To test the effect of the SMA intervention on A1C change, differences in change scores were compared between the ALDEA SMA intervention group and the UPC. Change scores were operationalized as the reduction in A1C at 3 months (3 months - baseline) and reduction at 6 months (6 months - baseline). Multiple linear regression analyses were conducted to assess if mean A1C change from baseline to 3 and 6 months was greater among SMA intervention group patients compared to the UPC control group patients. Baseline A1C and clinic (site) were entered as covariates in the model. Regression

analysis is an approach that has been supported in the literature as a valid method to examine change scores.²² Moreover, it provides data that are more easily interpretable in the clinical setting, for example, the difference in the amount of change in A1C (change score) between intervention and control groups.

Logistic regression analyses were conducted to test the effect of the SMA intervention on achieving target goals for BP and LDL at 6 months. These variables were dichotomized and coded as on target (1) and not on target (0); BP <140/90 and LDL <100 per current guidelines.²³ Clinic (site) was entered as a covariate in the model.

Results

Sample

Site 1: The nonprobability convenience sample consisted of 84 patients receiving primary care at an FQHC clinic, with the SMA intervention group (*n* = 29) and UPC control group (*n* = 55). A ratio of 2 to 1 was chosen to achieve sufficient power.

There were a total of 24 SMA sessions during the first 6 months of the program. The mean age of the SMA group was 55 years \pm 12, sex of patients was balanced across groups, with equal numbers of females and males in each group. Approximately half the SMA group was of Latinx origin and monolingual Spanish speaking. All of the patients were at or below 100% of the federal poverty line and had similar rates of health insurance. At baseline, there were no statistically significant differences in age (*P* = .32), sex (*P* = .58), poverty, or health insurance status (*P* = .84) between the SMA intervention group and the matched UPC control group (Table 2).

Site 2: The nonprobability convenience sample consisted of 55 patients receiving primary care at an FQHC clinic, with the SMA intervention group (*n* = 18) and UPC control group (*n* = 37).

There were a total of 12 SMA sessions during the first 6 months of the program. Each session included a mean of 7 patients. The mean age of the sample was 53 \pm 11 years. All of the patients were at or below the federal poverty line, and approximately 67% had health insurance (Table 2). At baseline, there were no statistically significant differences in age (*P* = .92), sex (*P* = .86), poverty level, or health insurance status (*P* = .78) between the SMA intervention group and the matched UPC control group.

Table 2

Demographic Characteristics of Study Participants

	Site 1			Site 2		
	SMA (n = 29)	Control (n = 55)	P	SMA (n = 18)	Control (n = 37)	P
Age, y, mean (SD)	55 (± 11.7)	55 (± 11.7)	.32	53 (± 11.2)	53 (± 10.6)	.92
Sex (% F/M)	50/50	50/50	.58	72/28	73/27	.86
Ethnicity, %						
Latinx	56.7	44.8		100	100	
African American	13.3	10.3				
American Indian/Alaskan Native	3.3	1.7				
Asian	6.7	10.3				
White	20.0	31.0				
Native language, %						
English	56.7	56.4				
Spanish	43.3	48.3		100	100	
Hmong		3.4				
Tagalog		1.7				
Declined		3.4				
% Below 100% federal poverty level	100	100		100	100	
% Has insurance	73	70	.84	65	68	.78

Table 3

Clinical Characteristics of Study Participants

Clinical parameters	ALDEA SMA (n = 29)		Control (n = 55)		P
Site 1	M	SD	M	SD	
A1C, baseline	9.75	1.86	9.73	1.97	.95
A1C, month 3	8.82	1.44	9.29	1.74	.28
A1C, month 6	8.63	1.91	9.30	2.13	.23
Site 2	n = 18		n = 37		
A1C, baseline	9.12	1.90	8.89	1.60	.69
A1C, month 3	7.93	1.49	9.2	2.26	.08
A1C, month 6	7.39	1.71	7.79	1.79	.51

Abbreviation: SMA, shared medical appointment.

Table 4

Changes in A1C at 3 Months and 6 Months: SMA Participants Versus Control Participants (Controlling for Baseline A1C)^a

SMA Predicting A1C Change ^b	n	b	SE β	t Statistic	P	Model Statistics
At 3 months	85	−0.71	−0.19	−2.23	.03	$F(3, 82) = 14.7, P = .00$
At 6 months	101	−0.80	−0.21	−2.34	.02	$F(3, 98) = 11.5, P = .00$

^aIntervention (SMA = 1, control = 0). SMA, shared medical appointment.
^bChange is defined as A1C at 3 months or at 6 months minus baseline A1C.

Table 5

SMA Predicting LDL and BP at Goal: SMA Versus Control at 6 Months^a

	n	b	SE β	Wald	P
BP	127	0.27	0.45	0.36	.55
LDL	125	0.64	0.40	2.61	.11

^aIntervention (SMA = 1, control = 0). BP, blood pressure; LDL, low density lipoprotein; SMA, shared medical appointment.

A1C

Cross-sectionally, there were no statistically significant differences on average A1C values between SMA and control groups at baseline, 3 months, and 6 months for either clinical site. (Table 3).

Multiple regression analysis demonstrated that compared to the UPC, the SMA group had a statistically significant change in A1C at 3 months, $F(3, 82) = 14.7, P = .00$, and 6 months, $F(3, 98) = 11.5, P = .00$ (Table 4). There was an additional reduction of A1C of −.71%, $b = -0.71, t(2) = -2.23, P = .03$, from baseline to 3 months and a statistically significant reduction of −.80%, $b = -0.80, t(2) = -2.34, P = .02$, from baseline to 6 months, in favor of SMA participants. The clinic site was not significant in the model (.34%), $b = .34, t(1) = 1.04, P = .30$, at 3 months, but it was at 6 months in favor of site 1 (.78%), $b = 0.78, t(1) = 2.29, P = .02$.

Logistic regression analyses showed no significant difference between SMA and UPC control group patients in achieving BP target, $b = 0.27, \text{Wald}(1) = .36, P = .55$, or LDL target, $b = 0.64, \text{Wald}(1) = 2.6, P = .11$, at 6 months. Clinic site was not significant predicting BP, $b =$

0.27, $\text{Wald}(1) = .36, P = .55$, or LDL $b = 0.64, \text{Wald}(1) = 2.61, P = .11$ (Table 5).

Discussion

The ALDEA SMA program, a culturally adapted, community-based SMA model, provided in 2 different community clinics was successful in reducing A1C among a socioeconomically and ethnically diverse group of patients.

The impact on A1C was clinically and statistically significant. The ALDEA SMA intervention led to a statistically significant greater reduction in A1C at 3 and 6 months compared to UPC patients. The SMA patients had an additional A1C drop of −0.71% at 3 months and −0.80% at 6 months, compared to those in UPC. The UKPDS provides us with a context to understand the clinical significance of these findings. The UKPDS demonstrated that a 1% decrease in A1C represents a 14% decrease in the risk of future macrovascular disease, 37% decrease in microvascular complications, and a 21% decrease risk of deaths related to diabetes.¹⁶

Furthermore, it is interesting that clinic site was a significant predictor in A1C reduction 6 months, in favor of clinic site 1, which offered weekly SMA groups. This may point to an important factor to consider when planning the periodicity of the program. Perhaps having it available on a weekly basis allowed for a higher level of engagement among participants. Currently, the exact mechanism for the improvement seen in A1C in the ALDEA SMA is unknown. Future research may evaluate factors that contribute to behavioral change. It is likely a combination of increased access to care and intensification of treatment in synergy with psychosocial and education support. Language concordance might also be a significant factor. It is well established that language and cultural concordance between providers and patients increase health outcomes for patients

with chronic conditions, including diabetes.²⁴ In rural settings, oftentimes, there are few providers who speak multiple languages. Some of the patients had concordance with their primary care provider in the usual care group, whereas all of ALDEA SMA patients did since this program was delivered by language-concordant providers.

Although this study was novel and had important clinical findings, there were limitations. The design did not randomize the patients to the SMA intervention group or UPC control groups. Patients self-selected to enroll in the SMA, which may have led to selection bias. Although the design matched participants by A1C and age, there are many other potential variables that could have influenced the results that are not accounted for in this design. Despite this, results from this study provide the foundation for designing a more rigorous, prospective randomized trial in the future.

Another limitation is the threat to internal validity. It is possible that there was a design contamination since the treatment and UPC control groups were at the same clinic and for many of the patients, the medical providers crossed over from SMA to UPC. Furthermore, the implementation of the ALDEA SMA program might have influenced primary care providers to intensify treatment and education efforts of the control patients. This bias could have underestimated the outcomes found in the study.

Despite its limitations, this study contributes to the existing literature and corroborates the finding of the first ALDEA SMA study as evidence of the effectiveness of the SMA model in reducing A1C among ethnic minority and medically underserved populations.¹⁵ Future research should include a more rigorous methodology, such as randomized control studies, and aim to include large samples that would provide sufficient power for the exploration of which elements within the SMA contribute the most toward positive behavioral changes and improvement in metabolic outcomes.

The ALDEA model has been successfully adapted and implemented in low-resource settings where large multidisciplinary professional teams are not financially sustainable. This study provides us with evidence that a small multidisciplinary team lead by 1 provider (MD or NP) with the support of a medical assistant and health educator can bring about significant improvements in A1C among medically underserved people living with type 2 diabetes. Thus, the ALDEA SMA model has the potential to reduce health disparities in diabetes outcomes among medically underserved communities.

Recommendations

The implementation of the ALDEA program in FQHCs provided valuable lessons to be considered in future interventions. First, it reinforced the value of language and cultural concordance between patient population and provider team. It demonstrates that programs that consider structural barriers can be successful. In this case, an open enrollment and a late policy that explicitly permitted late arrivals provided the flexibility needed for patient populations facing many structural barriers. Lastly, it reinforced the importance of an empowerment framework to increase patient activation and participation in DSMES programs. In sum, the ALDEA program demonstrated that medically underserved patients are eager to participate in community interventions that remove structural and cultural barriers to care. Educational programs must consider cultural and structural barriers in their program design.

ORCID iDs

Carolina Noya  <https://orcid.org/0000-0001-7403-9977>

Elizabeth Gatewood  <https://orcid.org/0000-0002-9974-0185>

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